

Before the Food and Drug Administration

Comments on FDA Docket No 2006D-0504 Draft Guidance for Industry and FDA Staff:
Radio Frequency Wireless Technology in Medical Devices

IEEE 802¹, as a leading consensus-based industry standards body, produces standards for wireless networking devices, including wireless local area networks (“WLANs”), wireless personal area networks (“WPANs”), wireless regional area networks (“WRANs”) and wireless metropolitan area networks (“Wireless MANs”). IEEE 802.18 is the Radio Regulatory Technical Advisory Group and it provides monitoring of, and active participation in, ongoing radio regulatory activities, at both the national and international levels.

Response of IEEE 802.18:

The Institute for Electrical and Electronics Engineers (IEEE) 802.18 Radio Regulatory Technical Advisory Group (“IEEE 802.18” or “the RR-TAG”) within IEEE 802, hereby submits its comments in the above captioned proceeding. This document was prepared and approved by the RR-TAG and also was reviewed by the IEEE 802 Executive Committee.²

Members of IEEE 802 are currently developing a wide range of wired and wireless networking standards that fit under the broadband access umbrella. Therefore, the members of the RR-TAG that participate in the IEEE 802 standards process are interested parties in this proceeding. We appreciate the opportunity to provide these comments to Federal Drug Administration (FDA).

The IEEE 802.18 RR-TAG is supportive of FDA’s work to characterize Radio-Frequency Technology in Medical Devices, and is looking forward to working with other organizations on these important issues.

The recent successes of IEEE 802 standards in medical environments is a testament to the market acceptance of devices that use RF to communicate data wirelessly. One of the foundations for this success is the access to unlicensed spectrum for these communications. These systems are easy to deploy, robust and a relatively inexpensive adjunct to hard wiring a network in a dynamic environment. However, the basic spectrum access conditions for unlicensed spectrum are that these devices must accept interference from other unlicensed devices and from primary and secondary users of the spectrum.³

These technologies are excellent for non-time sensitive communications such as email or non-emergency VoIP applications. Quality of service, data security and other features are provided via a layering of standards, the combination of which provide the improvements to the native best

¹ The IEEE 802 LAN/MAN Standards Committee develops Local Area Network standards and Metropolitan Area Network standards. An individual Working Group provides the focus for each area. More information about each group can be found at: <http://ieee802.org/dots.html>

² This document represents the views of IEEE 802.18. It does not necessarily represent the views of the IEEE as a whole or the IEEE Standards Association as a whole.

³ Unlicensed bands rules, CFR 47, Part 15, Subpart C
ISM Band FCC rules, CFR 47, Part 18, Subpart C, Technical Standards

effort services necessary for more demanding applications. IEEE 802.18 does not recommend or in any way suggest that the native best effort network technologies should be relied upon in critical situations where lives may be threatened by communication delays or QoS issues unless profiles of standards are specified to provide the necessary improvements in robustness.

IEEE 802 networks, both wired and wireless, offer layers of protection to the link. However, these link mechanisms may need to be part of a larger security approach to secure the data per HIPAA requirements.

Because of the nature of the work that the IEEE 802 Standards group undertakes, the areas of comment that the 802.18 RR-TAG has addressed in the document is limited to the scope of IEEE 802 standards, which are but a small subset of the issues discussed in the FDA document.

It is our intent in submitting these comments to assist the FDA in evaluating the issues raised in its proceeding with respect to wireless networks. We look forward to working with the FDA and other organizations in this matter.